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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,174	03/15/2005	Henryk Struszczyk	7007USO1	6038

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EXAMINER	
WHITE, EVERETT NMN	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,174	STRUSZCZYK ET AL.	
	Examiner	Art Unit	
	Everett White	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6 and 7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6 and 7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed August 14, 2006 has been received, entered and carefully considered. The amendment affects the instant application accordingly:

(A) Claims 4 and 5 have been canceled;
(B) Claim 1 has been amended;
(C) Comments regarding Office Action have been provided drawn to:
  (I) 102(b) rejections, which has been withdrawn;
  (II) 103(a) rejectionw, rendered moot by new ground of rejection over newly cited US Patent.

2. Claims 1-3, 6 and 7 are pending in the case.

Claim Rejections - 35 USC § 103

(New Ground of Rejection)

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-3, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Struszczyk et al (WO 01/87988, already of record).

Applicants claim a method for deproteinizing chitosan, comprising the steps of: (a) reacting an acidic solution of chitosan, said chitosan containing proteins ≥ 0.001 wt%, with an aqueous base to precipitate microcrystalline chitosan, and adding a first aqueous basic solution to reach $6.0 \leq pH \leq 6.5$ and then adding a second aqueous basic solution, wherein the concentration ratio of alkali in said first aqueous basic solution to said second aqueous basic solution is between 1:0.1 to 1:0.9; and (b) separating said precipitated microcrystalline chitosan from dissolved proteins to produce a microcrystalline chitosan having a protein content ≤ 10 ppm.

The Struszczyk et al WO publication discloses a process for preparing chitosan particles wherein the process involves precipitation of dissolved chitosan from an acid solution thereof by step-wise addition of a neutralizing agent to the solution. The neutralization is carried out under shear agitation at a pH within the range of 5.0 to 6.9, wherein the pH range covers the pH range disclosed in instant Claim 1. The Struszczyk et al publication further discloses homogenizing the neutralized chitosan and further subjecting the homogenized chitosan to further neutralization under shear agitation to a pH of above 6.9 (see abstract). The Struszczyk et al publication discloses that the further neutralization step produces a suspension of discrete particles of chitosan, which is washed, with water, to remove therefrom any residual soluble salt impurities, which embraces step (b) of instant Claim 1 . The chitosan particles may than be concentrated and recovered in conventional manner (see page 5, 4th paragraph), which embraces the procedures disclosed in instant Claim 6. See page 3, last paragraph of the Struszczyk et al publication wherein acid condition containing the chitosan is formed using acids that may be selected as, for example, acetic acid, lactic acid, and hydrochloric acid, which are identical to the acids listed in instant Claim 2. See page 4, 5th paragraph of

the Struszczyk et al publication, wherein the neutralization agents that can be used may be selected as hydroxides such as sodium and potassium, which is identical to the sodium hydroxide and potassium hydroxide disclosed in instant Claim 3. Also, see page 2, the first sentence of the 3rd paragraph of the Struszczyk et al publication, wherein it is disclosed that the invention thereof provides a process for preparing particles of "microcrystalline" chitosan, as indicated in instant Claims 1 and 7.

The method of deproteinizing chitosan in the instant claims differs from the method disclosed in the Struszczyk et al publication by claiming to produce a microcrystalline chitosan having a protein content ≤ 10 ppm.

However, in view of the similarities of the process steps disclosed in the Struszczyk et al publication to the process steps disclosed in the instantly claimed method and the preparation of closely similar microcrystalline chitosan products, the protein content obtained in the instantly claimed process is inherently obtained in the process disclosed in the Struszczyk et al publication. Applicants are reminded that under the principles of inherency, if a prior art device, in its normal and usual operation, would necessarily perform the method claimed, then the method claimed will be considered to be analogous to the prior art device. When the prior art device is the same as a device described in the specification for carrying out the claimed method, it can be assumed the device will inherently perform the claimed process. In re King, 801 F.2d 1324, 231 USPQ 136 (Fed. Cir. 1986).

One having ordinary skill in the art would have been motivated to employ the process of the prior art with the expectation of obtaining the desired product because the skilled artisan would have expected the analogous starting materials to react similarly.

Summary

5. All the pending claims are rejected.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Examiner's Telephone Number, Fax Number, and Other Information

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is 571-272-0660. The examiner can normally be reached on 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

E. White

Shaojia A. Jiang
Supervisory Primary Examiner
Technology Center 1600